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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,676	09/27/2001	Yem Chin	BSX-219	8991

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FULBRIGHT & JAWORSKI L.L.P.
801 Pennsylvania Avenue, N.W.
Washington, DC 20004-2615

EXAMINER

ROBERTS, PAUL A

ART UNIT PAPER NUMBER

3731

DATE MAILED: 06/18/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,676

Applicant(s)

CHIN ET AL.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 4, 8, 15, 19, 24, 30 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 5-7, 9-14, 16-18, 20-23, 25-29, 31, 32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 3, 5, 6, 7, 9, 27, 28, 29, 31, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Farascioni et al. US 6,142,955.

1. Regarding claim 1, Farascioni discloses an endoscopic needle knife with radiopaque markings along the length of the cutting member (figure 8; col. 15, 20-23.)
2. Regarding claims 2, 3, 6, 7, 27, 28, 29, 31, and 32, the lines shown in figure 8 act as reference points to determine the length of the deployed cutting member.
3. Regarding claims 5 and 9, the structure resulting from, “referencing the middle of the cutting member...” is a striated cutting device. Though Farascioni does not disclose the method of placing indicia on the cutting member, the result of his method of placing the indicia is shown in figure 8. The resulting device anticipates the limitations of claims 5 and 9 because Farascioni illustrates (in figure 8) a striated cutting member.

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4. Claims 10, 11, 21, 22, 23, 25, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Werner US 5,779,724. Werner discloses a surgical endoscopic catheter containing a needle knife on the end. The catheter shown in figure 2 contains evenly spaced detents (50), which interact with notch (64) on the distal end. The cable actuation is brought forth by spring 58, figure 5.

5. Regarding claims 21, 22, 23, and 34, the cutting member has detents (50), which also act as a visual indicator as to extent of extension of the surgical blade.

6. Regarding claim 25, the method step, "referencing the middle of the cutting member..." is not given any patentable weight since the step fails to recite any structural limitations. However, the Werner device is capable of being referenced in the aforementioned manner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 12, 13, 14, 16, 17, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werner '724 in view of Farascioni et al '955. Werner discloses a surgical endoscopic catheter containing a needle knife on the end. The catheter contains evenly spaced detents (50), which interact with one notch (64) on the distal end. Werner fails to disclose an endoscopic needle knife with radiopaque markings along the length of the cutting member. Farascioni teaches an endoscopic needle knife with radiopaque markings along the length of the

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cutting member (figure 8; col. 15, 20-23.) Farascioni states the motivation for including the radiopaque markings is that they would “indicate the longitudinal spacing of tissue basket 434 in order to provide the user with an indication of the tissue sampling area.” At the time of the invention it would have been obvious to modify the Werner surgical catheter by including the radiopaque markings as taught by Farascioni for the purpose of providing “the user with an indication of the tissue sampling area”

8. Regarding claims 13, 14, 17, and 18, the lines, shown in figure 9, act as reference points to determine the length of the deployed cutting member.

9. Regarding claims 16 and 20, the method step, “referencing the middle of cutting member...” is not given any patentable weight since the step fails to recite any structural limitations. However, the Werner device is capable of being referenced in the aforementioned manner.

10. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farascioni et al. ‘955 in view of Dretler et al. WO 01/01869 A1. Farascioni et al. disclose all of claim 21, but do not disclose that the visual indicia should include different color markings. Dretler et al. teach a visualizing indication system on an endoscopic tool (10-15, pg. 11), wherein “those markings assist the user in determining whether the helical coil [knife] is with or without sheath [extended or contracted.]” Thus providing the user a visual indicator of the knife’s position. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the Farascioni et al. device to include colored visual indicia for the purpose of assisting the user in determining whether the knife’s position and level of extension.

Response to Arguments

11. Regarding applicant's argument to rejection # 1 above, the cutting member of the Farascioni et al. reference includes the items of figure 39, items 46, 42, 414, 416, and 458. Since Farascioni et al. "Farascioni" discloses the element 458 has radiopaque markings, Farascioni anticipates all limitations of claim 1.

12. Regarding applicant's argument to rejection # 2 above, the lines on the Farascioni device are capable of being referenced to determine the length of the deployed cutting member. In response to applicant's argument that figure 8 does not disclose the lines *acting as reference points*, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The lines are clearly capable of acting as reference points. It appears the applicant is arguing that element 92 does not have radiopaque markings. While it is true Farascioni does not disclose that said lines have radiopaque attributes, element 458 is the part of the cutting member that contains said radiopaque lines (col. 15, 20-23.) See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

13. Regarding applicant's argument to rejection # 3 above, claims 5 and 9 state the method in which the lines are referenced. This is intended use of the device. Nevertheless, the Farascioni device is capable of being referenced so that an operator references the indicia starting from the centermost indicia of the Faracioni device and alternating which indicia the operator references as a function of distance from the middle of the device.

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14. Regarding applicant's argument to rejection # 4 above, element 72 is the catheter. A catheter is merely a hollow tube. Element 46 is the needle knife. A cable is a cylindrical object that is substantially longer than it is wide. A coiled spring meets the limitations of a cable. Thus element 58 is the cable that actuates the blade.

15. Regarding applicant's argument to rejection # 5 above, the cutting member comprises elements in figure 2, items 46, 92, 90, and 42. Element 42 contains detents 50. Detents are visual indicia.

16. Regarding applicant's argument to rejection # 6 above, claim 25 states the method in which the lines are referenced. This is intended use of the device. Nevertheless, the Werner device is capable of being referenced so that an operator references the detents starting from the centermost detent of the Werner device and alternating which detent the operator references as a function of distance from the middle of the device.

17. Regarding applicant's argument to rejection # 7 above, the catheter is element 72. The argument regarding the indicia on the cutting member of the Farascioni reference has been rebuffed in paragraph number 11 above.

18. Regarding applicant's argument to rejection # 8 above, the combined Werner device would have the Farascioni radiopaque markings near element 92 in figure 2, (shown but not labeled in figure 9). These markings would provide the user with reference points to determine the position of the blade. The examiner never stated the applicant's invention is obvious over Farascioni in view of Warner. So that argument is moot.

19. Regarding applicant's argument to rejection # 9 above, claims 16 and 20 state the method in which the lines are referenced. This is intended use of the device. Nevertheless, the combined

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Werner device is capable of being referenced so that an operator references the indicia starting from the centermost indicia of the Werner device and alternating which indicia the operator references as a function of distance from the middle of the device.

20. Regarding applicant's argument to rejection # 10 above, Farascioni discloses all of claim

21. Farascioni discloses (in figure 32) a catheter 76 which comprises (in figure 39) the cutting member, items 46, 42, 414, 416, and 458. The visual indicia are disposed on element 458. The colored visual markings of Dretler et al. would aid the user in determining whether the blade is withdrawn or extended. Thus one of ordinary skill in the art would have found it obvious at the time the invention was made to modify the Farascioni indicia to additionally comprise the Dretler et al. markings because Dretler et al. discloses that these markings make the process of determining if the blade is extended or withdrawn easier.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5810807 A "A sphincterotome with deflectable cutting plane and method of using the same."

US 5968061 A "Endoscopic surgical instrument for the implementation of endoscopic surgical procedures."

US 5951580 A "Scalpel having two blades adjustably separable."

US 6290721 B1 "Tubular medical endoprotheses"

US 6497709 B1 "An endoprosthetic filter system"

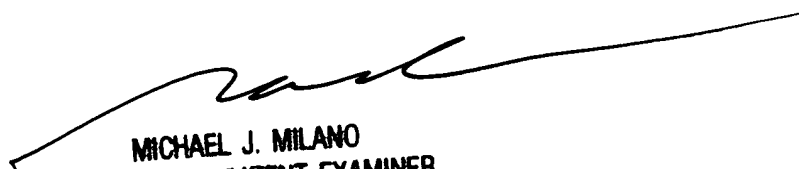
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
June 14, 2003



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700